

Exhibit M

PREP Act 5th Amendment

Billing Code: 4150-37

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

ACTION: Notice of amendment.

SUMMARY: The Acting Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID-19 vaccines that are covered countermeasures under section VI of this Declaration.

DATES: This amendment is effective as of January 28, 2021

FOR FURTHER INFORMATION CONTACT: Nikki Bratcher – Bowman, Acting Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Countermeasures under the PREP Act.

On January 31, 2020, the former Secretary Alex M. Azar II declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation’s health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration effective on April 26, 2020, July 25, 2020, October 23, 2020, and January 21, 2121.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause. (85 FR 35100, June 8, 2020) On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use



PREP Act

Public Readiness and Emergency Preparedness (PREP) Act Overview
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Legal Authorities

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of the Covered Countermeasures. (85 FR 51236, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary's Declaration and authorizations issued by the Department's Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections; made explicit that there are substantive federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the declaration in full. (85 FR 79190 December 9, 2020).

The Acting Secretary now amends section V of the Declaration to add additional categories of qualified persons covered under the PREP Act, and thus authorizes:

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or as authorized under section V(d) of this Declaration, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID-19 vaccination effort by a federal, State, local, Tribal, or territorial authority or by an institution in the State in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of the Inspector General, subject to:

(i) documentation of completion of the Centers for Disease Control and Prevention COVID-19 (CDC) Vaccine Training Modules¹ and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID-19 vaccine(s) to be administered; and

(g) Any physician, advanced practice registered nurse, registered nurse, or practical nurse who has held an active license or certification to prescribe, dispense, or administer vaccines under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a federal, State, local, tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline, or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of the Inspector General, subject to (i) documentation of completion of the Centers for Disease Control and Prevention COVID-19 Vaccine Training Modules and (ii) documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID-19 vaccine(s) to be administered.

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a "qualified person" is a "covered person." Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure. "Qualified person" includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) "a person within a category of persons so identified in a declaration by the Secretary" under subsection (b) of the PREP Act. 42 U.S.C. 247d–6d(i)(8)

By this amendment to the Declaration, the Acting Secretary identifies two additional categories of persons who are qualified persons under section 247d–6d(i)(8)(B), allowing healthcare providers who are licensed in a State to prescribe, dispense, and/or administer COVID-19 vaccines in any State or jurisdiction where the PREP Act applies, and allowing physicians, registered nurses, and practical nurses whose licenses expired within the past five years to prescribe, dispense, and/or administer COVID-19 vaccines in any State.

The Acting Secretary has determined that there is an urgent need to expand the pool of available COVID-19 vaccinators in order to respond effectively to the pandemic. As vaccine supply is made more widely available over the coming months, health care system capacity and the vaccination workforce are likely to become increasingly strained throughout the Nation. Permitting Physicians, registered nurses, and practical nurses who have recently expired licenses also significantly expands the vaccination workforce. There are approximately 160,000 inactive physicians and 350,000 inactive registered nurses and practical nurses in the United States.

These healthcare professionals can safely administer COVID-19 vaccines because they all have training in performing injections and observing for side effects and will be required to document completion of the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccine Training Modules.

Including these healthcare professionals as Qualified Persons under this amended Declaration achieves two purposes. First, the healthcare professionals will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. Second, any State law that would otherwise prohibit the healthcare professionals who are a "qualified person" from prescribing, dispensing, or administering COVID-19 vaccines is preempted. On May 19, 2020, the Office of the General Counsel issued an advisory opinion concluding that, because licensed pharmacists are "qualified persons" under this declaration, the PREP Act preempts state law that would otherwise prohibit such pharmacists from ordering and administering authorized COVID-19 diagnostic tests.² The opinion relied in part on the fact that the Congressional delegation of authority to the Secretary under the PREP Act to specify a class of persons, beyond those who are authorized to administer a covered countermeasure under State law, as "qualified persons" would be rendered a nullity in the absence of such preemption. This opinion is incorporated by reference into this declaration. Based on the reasoning set forth in the May 19, 2020 advisory opinion, any State law that would otherwise prohibit a member of any of the classes of "qualified persons" specified in this declaration from administering a covered countermeasure is likewise preempted. In accordance with section 319F-3(i)(8)(A) of the Public Health Service Act, a State remains free to expand the universe of individuals authorized to administer covered countermeasures within its jurisdiction under State law.³

The plain language of the PREP Act makes clear that there is complete preemption of state law as described above. Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID-19 as it will enable States to quickly expand the vaccination workforce with additional qualified healthcare professionals where State or local requirements might otherwise inhibit or delay allowing these healthcare professionals to participate in the COVID-19 vaccination program.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19.

Section V of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID-19, as amended April 10, 2020, June 4, 2020, and August 19, 2020 and amended and republished on December 3, 2020 is further amended pursuant to section 319F-3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as republished at 85 FR 79190 (December 9, 2020).

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons

42 U.S.C. 247d-6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are "manufacturers," "distributors," "program planners," "qualified persons," and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. "Order" as used herein and in guidance issued by the Office of the Assistant Secretary for Health³ means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required. In addition, I have determined that the following additional persons are qualified persons:

- (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration;⁴
- (b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy),⁵ (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA authorized or FDA licensed COVID -19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

- i. The vaccine must be authorized, approved, or licensed by the FDA;
- ii. In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s);
- iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;
- iv. The licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;
- v. The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;
- vi. The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation;⁶
- vii. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;
- viii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;
- ix. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and
- x. The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.⁷ Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or as authorized under the section V(d) of this Declaration, who prescribes, dispenses, or administers COVID-19

vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID-19 vaccination effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of the Inspector General, subject to: (i) documentation of completion of the Centers for Disease Control and Prevention COVID-19 (CDC) Vaccine Training Modules⁸ and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID-19 vaccine(s) to be administered; and

(g) Any physician, advanced practice registered nurse, registered nurse, or practical nurse who has held an active license or certification to prescribe, dispense, or administer vaccines under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a federal, State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of the Inspector General, subject to (i) documentation of completion of the Centers for Disease Control and Prevention COVID-19 Vaccine Training Modules and (ii) documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID-19 vaccine(s) to be administered.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa-10 et seq. are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

2. Effective Time Period, section XII, add to the end of the section:

Liability protections for Qualified Persons under sections V(f) and V(d) of the declaration begin on INSERT SIGNATURE DATE and last through October 1, 2024.

Authority: 42 U.S.C. 247d-6d.

Dated:

/s/
Norris Cochran,
Acting Secretary,
Department of Health and Human Services.

¹ See [COVID-19 Vaccine Training Modules](https://www.cdc.gov/vaccines/covid-19/training.html), available at <https://www.cdc.gov/vaccines/covid-19/training.html>

² Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf> / (last visited Jan. 24, 2021). See also, Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2020, available at: <https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf> (last visited Jan. 24, 2021).

³ See [Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to), OASH, Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to>

order-and-administer-covid-19-tests.pdf (last visited Jan. 24, 2021); **Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act**, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021).

⁴ See, e.g., **Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act**, OASH, Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf> (last visited Jan. 24, 2021); **Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities**, OASH, Aug. 31, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf> (last visited Jan. 24, 2021); **Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act**, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); **Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing**, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021); **PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures**, Oct. 29, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf> (last visited Jan. 24, 2021) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

⁵ Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, “State-licensed or registered intern” (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. See **Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing**, OASH, Oct. 20, 2020 at 2, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

⁶ This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase “current certificate in basic cardiopulmonary resuscitation,” when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See **Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act**, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); **Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing**, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-guidance.pdf> (last visited Jan. 24, 2021).

⁷ See, e.g., **Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act**, May 19, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf> (last visited Jan. 24, 2021).

⁸ See **COVID-19 Vaccine Training Modules**, available at <https://www2.cdc.gov/vaccines/ed/covid19/index.asp> (last visited Jan. 23, 2021) <https://www.cdc.gov/vaccines/covid-19/training.html>.

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